510(k) SUMMARY

K071141

1.0 Submitted By

BD Biosciences
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JUN - 6 2007

Contact:

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Submission date

April 20, 2007

2.0 Device Name and Classification

a) BD™Tritest CD3/CD4/CD45 with Trucount Absolute count Tubes

b) 864.5220 Automated differential cell counter, GKZ class II

3.0 Intended Use

The BD TriTEST™ CD3FITC/CD4PE/CD45 PerCP reagent is a three-color, direct immunofluorescence reagent for identifying and enumerating percentages of T lymphocytes (CD3+) and T-helper/inducer (CD3+CD4+) cells in erythrocyte-lysed whole blood (LWB). When used with TRUCOUNT™ Absolute Count Tubes, the product produces absolute counts in cells/μL.

4.0 Basic description of the device

The BD TriTEST™ CD3FITC/CD4PE/CD45 PerCP reagent is a three-color, direct immunofluorescence reagent for identifying and enumerating percentages of T lymphocytes (CD3+) and T-helper/inducer (CD3+CD4+) cells in erythrocyte-lysed whole blood (LWB). When used with TRUCOUNT™ Absolute Count Tubes, the product produces absolute counts in cells/μL. If used with Becton

Dickinson flow cytometers, the product can be used with MultiSET™ software for analysis as an accessory, or customers may perform analysis using CELLQuest™, CELLQuest Pro™ or LYSYS™ II software.

The reagent vials and counting bead vials are packaged separately. Each vial of this reagent yields 50 tests. Each package of counting bead tubes yields 50 tests.

5.0 Predicate Device

The BD™Tritest CD3/CD4/CD45 with Trucount Absolute Count Tubes currently in distribution was originally cleared by CDRH in 1997 under the 510(k) number of K965053.

6.0 Comparison to the Predicate(s)

The modifications to the legally marketed device (BD™Tritest CD3/CD4/CD45 with Trucount Absolute Count Tubes) intends to extend the sample stability claim for EDTA from 48 to 72 hours

The Intended use and the indications of the modified device, as described in its labeling are the same as the intended use and indications for the original predicate device.

7.0 Summary of Performance Data

Performance data from validation testing supports equivalency.

This Summary of safety and effectiveness is being submitted in accordance with the requirements of compliance with SMDA 1990 and 21 CFR 807.92.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN - 6 2007

Nobuko Nakajima
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2350 Qume Drive
San Jose, California 95131-1807

Re: k071141
Trade/Device Name: BD Tritest CD3/CD4/CD5 with BD Trucount Absolute Count tubes
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: April 20, 2007
Received: April 24, 2007

Dear Mr. Nakajima:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K071141

Device Name: BD Tritest CD3/CD4/CD45 with BD Trucount Absolute Count tubes

Indications For Use:

- For use with any flow cytometer equipped with a 488 nm laser and capable of detection in the ranges: 510-545 nm, 562-607 nm, and >650 nm
- For use in erythrocyte-lysed whole peripheral blood
- For use with or without isotype control
- To characterize and monitor some forms of autoimmune disease
- To characterize and monitor some forms of immunodeficiency disease, such as in HIV- infected individuals

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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